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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,302

12/22/2005

Maria Torpo

P05,0367

3792

26574

7590

12/16/2008

SCHIFF HARDIN, LLP
PATENT DEPARTMENT
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EXAMINER

BEHRINGER, LUTHER G

ART UNIT

PAPER NUMBER

3766

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,302	Applicant(s) TORPO ET AL.	
	Examiner LUTHER G. BEHRINGER	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the communication received on 10/29/2008 concerning application no. 10/562302 filed on 12/22/2005.

Double Patenting

2. Applicant's arguments, see pages 12 and 13, filed 10/29/2008, with respect to claim(s) 27 – 33, 36 – 38, 41 – 43, 47 – 54, 57 – 59, 62 and 63 have been fully considered and are persuasive. The double patenting rejection of claim(s) 27 – 33, 36 – 38, 41 – 43, 47 – 54, 57 – 59, 62 and 63 has been withdrawn.

Response to Arguments

3. Applicant's arguments with respect to claim(s) 27 – 63 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claim(s) 27 – 36 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by **Salo et al. (US 2005/0102002, herein Salo)**.

Applicant defines diastolic heart failure as an abnormality in the diastolic function (See page 1 of specification under background). The examiner is interpreting diastolic dysfunction as an equivalent term to abnormal diastolic function.

With regard to **claim(s) 27 and 48**, Salo discloses a method and an implantable medical apparatus for detecting diastolic heart failure (DHF) comprising: a sensor adapted to interact with a heart to obtain information associated with functioning of the heart; and a DHF determining device supplied with said information that detects a DHF state of the heart from said information by determining, as a DHF parameter, a time duration of a predetermined phase of diastole of the heart, *diastolic performance parameter* [0027] and, upon detecting said DHF state, that emits an output signal indicating said DHF state, *diastolic performance based feedback loop* [0033].

Regarding **claim(s) 28 and 49**, Salo inherently discloses wherein said DHF determining device comprises a comparator, *pacing parameter optimization module 124*, that compares said time duration, *diastolic performance parameter*, with an upper limit value and a lower limit value to obtain a comparison result, said comparison result being indicative of said DHF state (Fig. 1B; [0031]).

With regard to **claim(s) 29 and 50**, Salo discloses wherein said DHF determining device comprises a calculating unit that calculates, from said information from said sensor, said time duration, as a time from an occurrence of peak blood flow velocity

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through the mitral valve of the heart to a time of occurrence of zero blood flow velocity through the mitral valve of the heart [0035].

Regarding **claim(s) 30 and 51**, Salo inherently discloses wherein said calculating unit determines said time duration by extrapolating said mitral blood flow velocity to zero, if an actual occurrence of zero blood flow velocity through the mitral valve does not occur before an atrial contraction of the heart [0029].

With regard to **claim(s) 31 and 52**, Salo inherently discloses wherein said calculating unit extrapolates the blood flow velocity to zero by determining a time derivative of blood flow velocity through the mitral valve shortly after said occurrence of said peak blood flow velocity through the mitral valve [0029].

Regarding **claim(s) 32 and 53**, Salo inherently discloses wherein said sensor senses an IEGM signal from the heart [0025], and wherein said calculating unit calculates the time of occurrence of said peak blood flow velocity through the mitral valve to the time of occurrence of zero blood flow velocity through the mitral valve from said IEGM [0035].

With regard to **claim(s) 33 and 54**, Salo discloses wherein said sensor is an impedance sensor that senses an impedance of the heart, *measure LV volume*, and wherein said calculating unit calculates the time from the occurrence of said peak blood flow velocity through the mitral valve to zero blood flow velocity through the mitral valve from said impedance [0029].

Regarding **claim(s) 36 and 57**, Salo discloses wherein said DHF determining device comprises a calculating unit that calculates, as said time duration, an isovolumic

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relaxation time (IVRT) from said information from said sensor, *time constant (tau)* related to a decrease in the left ventricular pressure [0027].

With regard to **claim(s) 37 and 58**, Salo discloses wherein said sensor detects an IEGM from the heart [0025], and inherently discloses wherein said calculating unit determines said IVRT from said IEGM [0031].

Regarding **claim(s) 38 and 59**, Salo discloses wherein said sensor is an impedance sensor that measures an impedance of the heart [0029], and inherently wherein said calculating unit calculates said IVRT from said impedance [0031].

With regard to **claim(s) 41 and 62**, Salo inherently discloses wherein said DHF determining device determines said time duration, respectively at predetermined time intervals, thereby obtaining a plurality of time durations, *diastolic performance feedback loop*, and comprises a memory in which said plurality of time durations are stored, *therapy history data* [0032 – 0033].

Regarding **claim 42**, Salo discloses wherein said DHF determining device determines said time duration respectively at a plurality of predetermined time intervals *diastolic performance feedback loop*, and comprises a comparator, *pacing parameter optimization module 124*, capable of comparing each of said time durations to an upper limit value to identify a first plurality of time durations above said upper limit value and respective first magnitudes of respective deviations of said first plurality of time durations from said upper limit value, and a second plurality of time durations below said lower limit value and second magnitudes of deviations of said second plurality of time durations from said lower limit value, and comprises a memory in which said first

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plurality of time durations, said first magnitudes, said second plurality of time durations, and said second magnitudes are stored, *therapy history data* [0032 – 0033] (Fig. 1B).

With regard to **claim(s) 43 and 63**, Salo inherently discloses wherein said DHF determining device determines said time duration at a plurality of different times, *diastolic performance feedback loop*, and determines changes in the respective time durations determined at said different times, and comprises a memory in which said changes are stored, *therapy history data* [0032 – 0033, 0046].

Regarding **claim 47**, Salo discloses an implantable cardiac pacemaker comprising: a pulse generator, **114**, that emits stimulation pulses; an electrode system, **110A & 110B**, adapted to interact with the heart of a subject to deliver said stimulation pulses to the heart in a pacing therapy regimen, a sensor adapted to interact with a heart to obtain information associated with functioning of the heart, **112 & 116**, and a DHF determining device supplied with said information that detects a DHF state of the heart from said information by determining, as a DHF parameter, a time duration, of a predetermined phase of diastole of the heart; and a control unit, *pacing parameter optimization module* **124**, connected to said DHF determining device and to said pulse generator, said control device controlling said pulse generator to modify said pacing therapy regimen dependent on said DHF parameter (Abstract, Figs. 1A & 1B).

With regard to **claim(s) 34, 35, 39, 40, 55, 56, 60 and 61**, Salo discloses utilizing an acoustic sensor or accelerometer to determine a diastolic performance parameter upon which the blood flow velocity is inherently based [0030 – 0031].

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claim(s) 44 – 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Salo et al. (US 2005/0102002, herein Salo)** in view of **Paul et al. (US 5,814,088, herein Paul)**.

Regarding **claim(s) 44 – 46**, Salo discloses all of the limitations as discloses above, but fails to disclose an alerting unit that emits a humanly perceptible alert.

However, Paul discloses an alerting unit that emits a humanly perceptible alert (Col. 2, Lines 13 – 32).

A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of utilizing an alerting unit to achieve notification of a patient of an alert situation. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Salo to include an alerting unit as taught by Paul, since notifying a patient of a problem can aid in the correction of that issue and potentially improve the patient's quality of life.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 form.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 8:00 - 5:30; 2nd Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766